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FILED

MAR 1 2 2008

BOARD OF PHARMACY

By:

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STATE OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

IN THE MATTER OF THE APPLICATION OF: :

Administrative Action

THOMAS CLOUGH, R.P.

29 RI 01688500

FOR REINSTATEMENT OF LICENSURE TO PRACTICE PHARMACY IN THE

STATE OF NEW JERSEY

ORDER OF REINSTATEMENT

This matter was opened to the New Jersey State Board of Pharmacy upon receipt of respondent's application for reinstatement of his license to practice pharmacy in this State. Respondent voluntarily surrendered his New Jersey license by way of a Consent Order filed with the Board on April 4, 2002 because of a relapse with regard to his prior substance abuse problem. Respondent had entered into two previous Consent Orders with the Board regarding allegations of diversion of Hycomine Syrup from the active drug stock of his then-employer, CVS Pharmacy. In the first order, entered August 26, 1994, respondent agreed to refrain from practice pending a plenary hearing before the Board, and the second, entered March 22, 1995 suspended respondent's license for three

years, with seven months of the suspension active. Respondent was subjected to urine monitoring for three years, and was not permitted to use or possess any Controlled Dangerous Substances except for documented bona fide medical purposes.

In the April 4, 2002 Consent Order, respondent agreed that to be considered for reinstatement he must submit documentation including weekly, random, witnessed urine screens, complete treatment records of all diagnostic and rehabilitative therapy and an in-depth, current evaluation from a Board approved psychiatrist or psychologist. He must also demonstrate competence to resume the practice of pharmacy. Respondent has now made re-application for the reinstatement of his pharmacy license.

On June 27, 2007 respondent appeared at an Investigative Inquiry before the Board and testified as to his history of involvement with the Professional Assistance Program of New Jersey ("PAPNJ"). The Board considered the testimony of respondent and David I. Canavan, M.D., Assistant Medical Director of PAPNJ at the inquiry. The Board also reviewed the statements of Louis E. Baxter, M.D., FASAM, Executive Medical Director of the PAPNJ and John A. Bostrom, M.D., staff psychiatrist of Care Plus NJ, the evaluations of Ricardo J. Fernandez, M.D. dated August 7, 2006 and July 18, 2007, and all relevant documentation submitted.

In addition, Louis E. Baxter, M.D., FASAM, Executive Medical Director of the PAPNJ, sent a letter supporting the reinstatement of respondent's license, contingent upon his continued treatment and monitoring. Specifically, Dr. Baxter stated that respondent has been in ongoing, documented recovery from dependence on Hydrocodone since March 2002 and from alcohol since August 2006. He provided documentation of respondent's completion of an outpatient program begun in August 2006 due to a relapse of alcohol abuse. Dr. Baxter also advised that respondent was diagnosed with bipolar disorder and is in treatment with a psychiatrist. In his testimony, Dr. Canavan indicated

that respondent is on medication for his bipolar disorder, which does not appear to be causing respondent any problems.

On October 3, 2007, the Board received a letter from David Canavan, M.D., Assistant Medical Director of PAPNJ, advising that respondent reported a one night "slip" in his program of alcohol recovery, and that as a result, respondent has intensified his treatment program. Dr. Canavan explained that PAPNJ considers an isolated one night episode a "slip" rather than a relapse, but any additional episode would constitute a relapse. Dr. Canavan requested that respondent's license be reinstated on the understanding that another "slip" would mean immediate suspension. Respondent supplied a letter to the Board dated January 7, 2008, concerning his lapse. He advised that he met and discussed the situation with Dr. Canavan and his counselor, and has taken steps to guard against future occurrences, including:

- 1. Increased meeting attendance to once daily;
- 2. Found a new sponsor with eight years of recovery;
- 3. Expanded support network in the recovering community;
- 4. Recognized lack of dependence on a Higher Power and has made efforts to improve that relationship;
- 5. Continued to see counselor and psychiatrist at Care Plus;
- 6. Resumed taking Campral, which he had not been taking during the time of the lapse.

It appears that respondent has now demonstrated sufficient rehabilitation, fitness and ability to practice pharmacy, respondent agrees to comply with the conditions set forth in this Order, and respondent has complied with the requirements of the prior Board Order, including providing the Board with the necessary records and information, obtaining positive evaluations from a mental health professional; he continues to have negative drug and alcohol screens; he immediately reported the brief lapse in his recovery; and he has completed the required continuing education.

Respondent, being desirous of resolving this matter without the necessity of further formal proceedings, and agreeing to waive any right to same, and the Board having determined that this Order is sufficiently protective of the public health, safety and welfare, and all parties agreeing to the terms of this Order;

IT IS THEREFORE ON THIS 12 th DAY OF March, 2008, ORDERED THAT:

- Respondent's license to practice pharmacy in the State of New Jersey is hereby reinstated subject to the conditions set forth in this Order.
- Respondent's license shall be placed on probation for a period of three
 years to commence on the filing date of this Order. Should respondent violate any of the conditions, the Board shall take further disciplinary action.
- 3. (a) Respondent shall submit to directly witnessed random urine monitoring a minimum of two (2) times per week at a laboratory facility approved by the Board for the initial twelve (12) months of license reinstatement and employment as a pharmacist, and a minimum of one (1) time per week for the twelve (12) months thereafter. The frequency of subsequent screening is to be determined by the PAPNJ. The urine monitoring shall be conducted with direct witnessing of the taking of the samples as designed by the laboratory facility. The initial drug screen of each sample shall utilize appropriate screening techniques and all confirming tests and/or secondary tests will be performed by gas/chromatography/mass spectrometry (G.C./M.S.). The testing procedure shall include a forensic chain of custody protocol to ensure sample integrity and to provide documentation in the event of a legal challenge.

(b) All test results including any secondary test results shall be provided directly to Joanne Boyer, Executive Director of the Board, or her designee in the event she is unavailable. The Board also will retain sole discretion to modify the manner of testing in the event technical developments or individual requirements indicate that a different methodology or approach is required in order to guarantee the accuracy and reliability of the testing. Upon receipt of any positive urine screen, the Board reserves the right to amend the within order or to take action as provided in paragraph 13 below.

(c) Any failure by respondent to submit or provide a urine sample within twenty-four (24) hours of a request will be deemed to be equivalent to a confirmed positive urine test. In the event respondent is unable to appear for a scheduled urine test or provide a urine sample due to illness or other impossibility, consent to waive that day's test must be secured from Joanne Boyer or her designee. Personnel at the lab facility shall not be authorized to waive a urine test. In addition, respondent must provide the Board with written substantiation of his inability to appear for a test within two (2) days, e.g. a physician's report attesting that he was so ill that he was unable to provide the urine sample or appear for the test. "Impossibility" as employed in this provision shall mean an obstacle beyond the control of respondent that is so insurmountable or that makes appearance for the test or provision of the urine sample so infeasible that a reasonable person would not withhold consent to waive the test on that day.

(d) In the event respondent will be out of the State for any reason, the Board shall be so advised so that arrangements may be made at the Board's discretion for alternate testing. The Board may, in its sole discretion, modify the frequency of testing or method of testing during the monitoring period.

- (e) Any urine test result showing creatinine levels below 20 mg/dL and a specific gravity below 1.009 shall create a rebuttable presumption of a confirmed positive urine test. Such a specimen shall be immediately subjected to the confirming GC/MS test.
- (f) Respondent shall familiarize himself with all foods, food additives or other products (such as poppy seeds) which may affect the validity of urine screens, be presumed to possess that knowledge, and shall refrain from the use of such substances. Ingestion of such substances shall not be an acceptable reason for a positive urine screen and/or failure to comply with the urine monitoring program.
- 4. Respondent shall abstain from all psychoactive substances, including alcohol and controlled dangerous substances, and shall not possess any controlled dangerous substances except pursuant to a <u>bona fide</u> prescription written by a physician or dentist for good medical or dental cause in his own treatment. In addition, respondent shall advise any and all treating physicians and/or dentists of his history of substance abuse. Respondent shall cause any physician or dentist who prescribes medication for him which is a controlled dangerous substance to provide a written report to the Board together with patient records indicating the need for such medication. Such report shall be provided to the Board no later than two (2) days subsequent to the prescription in order to avoid confusion which may be caused by a confirmed positive urine test as a result of such medication.
- 5. Respondent shall attend Alcoholics Anonymous/Narcotics Anonymous ("AA/NA") meetings or its equivalent at a minimum frequency of three (3) times per week for the duration of the three year probationary period. Respondent shall provide evidence of attendance at such groups directly to the Board on a monthly basis. If respondent

discontinues attendance at any of the support groups without obtaining approval of the Board he shall be deemed in violation of this Order.

- 6. Respondent shall continue to participate in an aftercare program with a Board approved psychologist until such time as the psychologist, in consultation with the Executive Director of the PAPNJ, determines that respondent's participation is no longer required. The Board is to be notified of the respondent's discontinuation in the aftercare program.
- 7. Respondent shall continue to participate in substance abuse counseling or psychotherapy with an addiction counselor, psychologist, psychiatrist, or mental health professional, at a minimum frequency of one (1) time per month, until such time as the PAPNJ recommends a modification to respondent's participation in counseling. Respondent shall ensure that his therapist or any successor therapist is pre-approved by the Board, provides quarterly reports to the Board regarding his progress in treatment and immediate (within 24 hours) reports to the Board orally and in writing of any indication of a slip, relapse or recurrence of drug or alcohol abuse directly to the Board.
- 8. Respondent shall be on Vivitrol (Naltrexone IM) for the first six (6) months of employment as a pharmacist, as recommended by Dr. Fernandez, and thereafter, as recommended by the PAPNJ or by respondent's psychiatrist.
- 9. Respondent shall maintain continued enrollment and face-to-face follow up with a clinical representative of the PAPNJ for the three (3) year probationary period, with quarterly reports to be provided by the PAPNJ to the Executive Director of the Board.

- 10. Respondent shall not act as a preceptor or a pharmacist-in-charge (RPIC) at any pharmacy and shall not own or have an ownership interest in any pharmacy for the three (3) year period of probation commencing on the entry of this Order.
- 11. Respondent shall provide any and all releases to any and all parties who are participating in the monitoring, treatment or other program as outlined in this Order, including but not limited to his psychotherapist, as may be required in order that all reports, records, and other pertinent information may be provided to, and utilized by the Board in a timely manner.
- 12. Respondent shall serve a copy of this Order on all employers, licensee supervisors, and/or responsible entities or officials at each and every facility where he plans to practice pharmacy, prior to commencing work as a licensee and shall ensure that each employer and licensee supervisor sends documentation to the Board that he or she has reviewed the complete Order.
- of his license for the remainder of the probation period upon the Board's receipt of any information which the Board, in its sole discretion, deems reliable demonstrating that respondent has failed to comply with any of the conditions set forth in this Order including but not limited to report of a confirmed positive urine or a <u>prima facie</u> showing of a slip, relapse or recurrence of alcohol or drug abuse.
- (b) Respondent shall have a right to apply for removal of the automatic suspension on ten (10) days notice to the Board and to the Attorney General. The Board may hold a hearing on that application before the full Board or before a committee of the Board. In the event a committee hears the application, its action shall be subject to

ratification of the full Board at its next scheduled meeting. In a hearing seeking removal of the automatic suspension, any confirmed positive urine shall be presumed valid.

- All costs associated with the PAPNJ, urine monitoring and employment 14. monitoring provisions outlined above shall be the responsibility of the respondent and paid directly by the respondent.
 - 15. This Order is effective upon its filing date with the Board of Pharmacy.

NEW JERSEY STATE BOARD OF PHARMACY

By: Kolward W. Mr Hinley Edward G. McGinley, R.Ph. Of President

Thave read the within Order, understand its terms and agree to be bound by them. I consent to entry of the Order by the Board of Pharmacy.

Thomas Clough, R.P.

Respondent